

K102295 X2ABS DUAL CHANNEL FITNESS BELTFeb 18, 2011
189 days to decisionK102295 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k102295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Aug 13, 2010
Decision date	Feb 18, 2011
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Leto Enterprises Incorporation
Location	Hong Kong, CN
Contact	SABRINA WEI
510(k) history	2 submissions · 2 cleared · 2011-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102295/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026